UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/489,079	01/21/00	BILLING-MEDEL	P 6451.US.P1

023492
ABBOTT LABORATORIES
DEPT. 377 - AP6D-2
100 ABBOTT PARK ROAD
ABBOTT PARK IL 60064-6050

HZ12/0904

EXAMINER	
EPPS, J	
ART UNIT	**PAPER NUMBER**
1635	15

DATE MAILED: 09/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No. 09/489,079	Applicant(s) BILLING-MEDEL ET AL.	
	Examiner Janet L. Epps	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *52-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

2. Newly submitted claims 62-69, and 71-76 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The newly submitted claims 62-69 and 71-76 are drawn to polynucleotide sequences and methods of using said polynucleotide, however the original elected invention was drawn to polypeptide sequences and methods of using said polypeptide sequences.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 62-69 and 71-76 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Newly added claims 52-61, 70, and 77-81, drawn to the elected invention in Paper # 7, are currently under examination.

Response to Arguments

4. Claims 52-81 are rejected under 35 U.S.C. 101 and 35 USC 112, first paragraph, for the reasons of record set forth in the Official Action mailed 10-24-2000, in the rejection of claims 23-25, 28-29, 36-37, 39-40, and 51 under 35 USC 101 and 35 USC 112, first paragraph.

Applicant's arguments filed 7-18-01 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that scientist skilled in the diagnostics arts using gene markers, a gene product, such as messenger RNA (mRNA) coding

for the protein, which is more prevalent and specific to one tissue type (the host tissue) than other tissue types, is extremely useful as a marker for the detection of disease in the host tissue. Additionally, Applicants argue that "[I]f a protein appears in a tissue or body component where the normal occurrence of the protein is very low or non-existent, then the specific tissue in which the protein is normally found is in a diseased state. However, contrary to Applicant's assertions, the factual information that applicants have provided to give credence to their claim of a patentable utility, is not supported by the specification as filed, or by a prior art reference. It is not evident from Applicant's arguments or the specification as filed that the BS322 polypeptide of the present invention is useful as a diagnostic for breast disease. The evidence provided by Applicants is clearly prophetic.

As stated in the prior Official Action, the specification as filed teaches that the BS322 consensus sequence was found in 23.2% (10 of 43) breast tissue libraries and found in only 0.1% (1 of 762) of other, non-breast libraries. According to Applicant's arguments set forth above, the presence of a protein in a tissue or body component where it is not normally found indicates the presence of disease. However, the specification as filed teaches that the BS322 is normally expressed at low levels in non-breast tissue libraries. Without further experimentation, it is unclear how one of skill in the art is to use a method for detecting the BS322 polypeptide in non-breast tissue, where the BS322 polypeptide is normally expressed, albeit at low levels, to diagnose the presence of a disease of the breast. The specification teaches the detection of the BS322 polypeptide, however there is no correlative evidence that would clearly indicate that detecting the presence of the BS322 polypeptide in non-breast tissues would provide a diagnosis for a breast disease. As indicated in the prior Office action, the specification as filed does not

disclose whether or not the non-breast tissue libraries used in the specification as filed, which indicated the low level of BS322 polypeptide, was associated with normal or malignant tissues, therefore rendering Applicant's findings inconclusive.

Additionally, Applicant's claims, particularly, claims 57-59, 65-69, 77-79, are not limited to detecting the presence of the BS322 polypeptide in non-breast tissues. Applicant's claims read on detecting the presence of the BS322 in a test sample, however the test sample may include both non-breast tissue and breast tissue. Therefore, detecting the presence of the BS322 polypeptide in breast tissue would reveal detection complexes, however it is unclear if the presence of detection complexes would indicate the presence of disease since the protein is normally expressed in these tissues.

Applicant's arguments do not take the place of evidence, the instant claims remain rejected for the reasons of record and for those set forth above.

5. Claims 52-61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims read on a genus of BS322 polypeptides having at least 90% identity over the entire length of a sequence selected from the group consisting of SEQ ID NO: 24-28 or SEQ ID NO:25-28. However, neither the claims nor the specification as filed indicate what distinguishing structural or functional attributes the members of the claimed genus of polypeptides share. The specification and claims do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to the claim

polypeptides, it is only required that a protein maintains 90% identity to the claimed polypeptide sequences. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between the genus members are permitted, and neither the specification nor the claims provide any guidance as to what specific changes should be made. Furthermore, there are no common functional attributes shared among the members of the claimed genus of polypeptides that would allow one of skill in the art to clearly distinguish the members of this genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is required. Since the disclosure fails to describe the common attributes or characteristics that identify the members of the genus, and because the genus is highly variant, the disclosed sequences of SEQ ID NO: 24-28 or 25-28 alone are not sufficient to describe the claimed genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

6. Claims 62-69, 72-76 and 80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 62-66, recite "[A] purified polynucleotide, selected from the group consisting of SEQ ID NOS: 25-28;" Claims 67-69 recite "the polynucleotide contains at least one epitope derived from a sequence selected from the group consisting of: SEQ ID NOS: 24-28;" Claims 72-76 recite "[A]n isolated DNA molecule, selected from the group consisting of: SEQ ID NOS: 25-28;" and Claim 80 recites "wherein said immunogenic polypeptide is a DNA molecule selected from the group consisting of: SEQ ID NOS: 24-28," these limitations recited in claims

62-69, 72-76 and 80 are vague and indefinite since the sequences recited in SEQ ID NOS: 24-28 are amino acid sequences and do not correspond to DNA molecules or polynucleotide sequences.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps whose telephone number is 703-308-8883. The examiner can normally be reached on Mondays through Friday, 9:00AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps
Examiner
Art Unit 1635

jle
August 31, 2001

JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600